

REMARKS

The Office Action of August 29, 2000 has been carefully considered. It is noted that:

the application is restricted and election is required;

the abstract is objected to for containing the word "said";

the Sequence Listing is required for full compliance;

claim 9 is objected to for containing a misspelled word "phosphoribosyl-transerase"; and

claims 1-17 are rejected under 35 U.S.C section 112, first paragraph for wanting an enabling disclosure, and under U.S.C section 112, second paragraph for being indefinite.

Claims 1-19 are pending in the present application. In connection with the restriction requirement, applicants hereby affirm that claims 1-17 have been elected for further prosecution. Applicants reserve the right to pursue the non-elected claims 18-19 in a divisional application prior to issuance of a patent on the instant application. By the present amendment, claim 1 has been amended, claims 2-17 are cancelled, and new claims 20-33 are added.

In connection with the Examiner's objection to the abstract, applicants have amended the abstract to replace "said" with "the". Thus, the objection is overcome and should be withdrawn.

In connection with the sequence listing requirement, applicants have submitted herewith a sequence listing both in a paper format and a computer-readable format.

The following remarks respond to the Examiner's rejection of the claims under 35 U.S.C section 112, first and second paragraphs:

Rejection of Claims 1-17 under 35 U.S.C. Section 112, First Paragraph

The Examiner rejected claims 1-7, which are drawn to a transgenic mouse model for spinal muscular atrophy, for lacking an enabling disclosure pursuant to 35 U.S.C. section 112, first paragraph. The Examiner's rejection is based on his belief that (i) a "transgenic mouse to be used as a model [for spinal muscular atrophy] must have complete complement and symptoms of human spinal muscular atrophy" (see Office Action page 7, paragraph 3) and (ii) the disclosed "evidence can not be extrapolated to the instantly broadly claimed invention" because some embodiments falling within the claim scope are not workable (see Office Action page 8, paragraph 2). It is respectfully submitted that both the Examiner's aforementioned arguments are without legal and scientific foundation.

With reference to the Examiner's first argument, it is respectfully submitted that the subject matter claimed in the present patent application is a transgenic mouse model for spin muscular atrophy and such a transgenic mouse model is useful in studying the corresponding human disease. To claim such a mouse model, 35 U.S.C. section 112, first paragraph, requires nothing more than a disclosure that teaches a person of ordinary skill in the art to make a mouse model as claimed. Please note that none of the pending claims requires a mouse model that displays a complete spectrum of the symptoms as they might be displayed in a human patient. Thus, the Examiner's requirement that the mouse model must display an identical spectrum of symptoms as a human patient may display is without legal basis. Nor is such a requirement scientifically sound. To applicants' knowledge, an identical disease may show varied symptoms in different human subjects, and one therefore should not expect an animal model to show an identical set of symptoms as a human patient may. Animal models

that mimic some symptoms of a human disease have been well known in the art to be useful in understanding the corresponding human disease.

Turning to the Examiner's second argument, claim 1 as amended recites a transgenic mouse harboring a mutation that affects the native *Smn*'s expression and a piece of human DNA that compensates to a certain degree the affected *Smn*'s functionality. Within the scope of claim 1, of course, there are many possible embodiments. However, 35 U.S.C 112, first paragraph, does not requires, as the Examiner seems to contend, that each and every possible embodiment within the claim scope must be workable and have the same utility. As the court in *Decca, Ltd. v. United States*, 544 F.2d 1070 (Ct.Cl. 1976), pointed out "[t]he mere fact that the system has some drawbacks, or that under certain postulated conditions it may not work ...does not detract from the operability of the disclosed equipment to perform its desired function." All that is required under 35 U.S.C 112, first paragraph, is a teaching that enables a person of ordinary skill to practice the claimed subject matter which, in this case, is to make a mouse harboring a mutation affecting *Smn*'s expression and a rescuing human DNA sequence. It is respectfully submitted that applicants in this case have provided clear instructions as to how to introduce a mutation affecting the expression of the *Smn* gene in the mouse genome and how to introduce a rescuing human DNA sequence thereto. Not only does the specification provide specific examples of the starting materials used to make such a transgenic mouse as in the preferred embodiment, it also provides guidance in selecting the operation parameters that would yield the desired result. For example, the mutation introduced in the mouse genome must be such that it affects *Smn*'s expression and the rescuing human DNA must be the ones that are capable of partially restoring the affected *Smn* functionality. It is respectfully submitted that people of ordinary skill in the art, most likely a molecular

biologist in this case, would know how to make a mutation that affects a specific gene expression and he or she would also know how to select a human DNA sequence that may supply the *Smn*-like functionality in the mouse. These were ordinary skills in the art as of the time when the present invention was made.

As to the specific example cited by the Examiner that a transgenic mouse with the same background (i.e. *Smn*⁻/*Smn*⁻) but harboring a SMN^T region might not exhibit any SMA like symptoms, it is respectfully submitted that such a possible scenario does not support the Examiner's rejection for three reasons. First, as mentioned above, the enablement law does not require all possible embodiments read on the claimed general inventive idea be perfectly workable. Second, a person skilled in the art would know, as it is demonstrated by the Examiner's own knowledge, that a copy of human SMN^T region is likely to completely restore the lost *Smn* functionality and thus may not produce a mouse showing any SMA-like symptoms. A person of ordinary skill is presumed not to deliberately choose an unworkable path in practicing the claimed invention. Third, selecting SMN^T as a rescuing human gene in practicing the invention is against the explicit guidance specified by the claim that requires the use of a rescuing gene that partially compensates the lost *Smn* functionality. The SMN^T gene, if the Examiner's assertion is true, would fully compensate the lost functionality.

In view of the foregoing arguments, it is respectfully submitted that the specification disclosed in the instant case provides an enabling teaching to make a transgenic mouse model as claimed in amended claim 1 and in newly added claims 20-33, and that the Examiner's rejection under 35 U.S.C. section 112, first paragraph, should be withdrawn.

Rejection of Claims 1-17 under 35 U.S.C. Section 112, Second Paragraph

Claims 1-17 also stand rejected under 35 U.S.C. section 112, second paragraph.

The Examiner's identification of various terms used in the claims which he considered as indefinite are noted. It is respectfully submitted that the word "partially" does not render a claim indefinite. "Partially" as used in claim 1 takes its ordinary meaning and does not need to be specifically defined. The ordinary meaning of "partially" is not ambiguous in the context of claim 1. According to one dictionary, "partially" means "not completely or wholly". Thus, the Examiner's rejection of the use of the word "partially" as indefinite simply because it is a "relative term" is without any legal basis and should be withdrawn. The remaining of the words or terms rejected by the Examiner as indefinite are no longer present in the claims now on file. Therefore, it is respectfully submitted that the Examiner's rejection under 35 U.S.C. section 112, second paragraph is overcome and should be withdrawn.

Reconsideration and allowance of the present application are respectfully requested.

It is believed no fees or charges are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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Dated: November 9, 2000